

# EXHIBIT A

<b>Opinions that the Court Permitted in the Class Certification Order [D.E. 2261]</b>	<b>Corresponding Opinions in Dr. Panagos’s October 31, 2022 Report</b>
12. In July 2018, the FDA announced a voluntary recall of Valsartan including Valsartan containing drugs (collectively referred to herein as “VCDs”) due to contaminants (NDEA and NDMA). These contaminants are probable human carcinogens according to the International Agency for Research on Cancer (IARC) classification.	16. In July 2018 and September 2018 respectively, the FDA announced a voluntary recall of VCDs due to contaminants NDEA (N-Nitrosodiethylamine) and NDMA (Nnitrosodimethylamine). These contaminants are probable human carcinogens according to the International Agency for Research on Cancer (IARC) classification. Subsequent recalls followed.
13. VCDs belong to a class of medications known as Angiotensin Receptor Binders (ARBs) and are the approved generics of the brand name drug, Diovan and Diovan HCT respectively.	13. Diovan and Exforge (collectively, the “Reference Listed Drugs”) are a class of medications known as Angiotensin Receptor Binders (“ARBs”). The FDA approved Diovan on August 3, 2005 and Exforge on June 20, 2007.
14. The term TPPs generally refers to entities (other than the patient or health care provider) that reimburse and manage healthcare expenses including prescription drug benefits or coverage. In this matter, TPPs are specifically defined to include: All TPPs in the United States and its territories and possessions that, since at least January 1, 2012 to the present, paid any amount of money for valsartan-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Active Pharmaceutical Ingredient, Finished Dose, Wholesaler, or Repackager/Relabeler Defendant.	20. The term TPPs generally refers to entities (other than the patient or health care provider) that reimburse and manage healthcare expenses including prescription drug benefits or coverage. It is my understanding that the Court will conduct a trial which will involve purchases paid for by SummaCare, Inc. (“SummaCare”) and EmblemHealth (“Emblem”), both of which are TPPs. These TPPs, as with most TPPs, both included generic VCDs on their drug formularies and reimbursed for purchases of these VCDs (intended for personal or household use). Many of these VCDs were manufactured, distributed, or sold by active pharmaceutical ingredient and finished dose manufacturers, including the relevant defendants here, Zhejiang Huahai Pharmaceuticals (“ZHP”), Teva Pharmaceuticals and Torrent Pharmaceuticals.
16. TPPs are the payors ultimately responsible, or at risk, for payments associated with their insureds’ purchases. Along with the consumers, all TPPs share this essential commonality of responsibility and risk as the ultimate payer. Consumers pay their portion (referred to as Copay) and TPPs pay the remaining portion (also referred to as “plan paid”).	21. SummaCare and Emblem are the payors ultimately responsible, or at risk, for payments associated with their insureds’ purchases. Consumers pay their portion (referred to as a copay) and SummaCare and Emblem pay the remaining portion (also referred to as “plan paid”).

17. TPAs manage claims processing, provider networks, utilization reviews, formulary, and membership.	22. TPPs manage claims processing, provider networks, utilization reviews, formulary, and membership.
18. The prescription drug pharmacy benefit represents eligible medications for reimbursement under the prescription drug benefit via the prescription formulary. The prescription drug benefit is different and apart from the medical benefit.	23. The prescription drug pharmacy benefit represents eligible medications for reimbursement under the prescription drug benefit via the prescription formulary. The prescription drug benefit is different and apart from the medical benefit.
19. A Pharmacy Benefit Manager (PBM) is a third-party administrator contracted to administer prescription drug plans for a variety of sponsors including commercial health plans, self-insured employer plans, union plans, Medicare Part D plans, and federal and state employee plans.	24. A PBM is a third-party administrator contracted to administer prescription drug plans for a variety of sponsors including commercial health plans, self-insured employer plans, union plans, Medicare Part D plans, and federal and state employee plans.
20. PBMs negotiate discounts off the purchase price of prescription drugs and pass those savings on to the payor. The “payor” could be an insurance company, commercial health plan, self-insured employer plan, Medicare Part D plan, Federal Employee Health benefit program, or state government plan. The PBM functions as the authorized agent on behalf of the third-party payor.	26. PBMs negotiate discounts off the purchase price of prescription drugs and pass those savings on to the payor. The “payor” could be an insurance company, commercial health plan, self-insured employer plan, Medicare Part D plan, Federal Employee Health benefit program, or state government plan. I attach as <b>Exhibit A</b> a chart showing the role that PBMs play in managing drug benefits and the related flow of payments.
21. PBMs often develop and manage drug formularies. The primary function of a formulary is to provide pharmacy care that is clinically sound and affordable for TPPs and their plan members and to help manage drug spend through the appropriate selection and use of drug therapy.	28. A prescription drug formulary is a list that specifies what drugs are covered under a medical plan and at what coverage amount. The primary function of a formulary is to provide pharmacy care that is clinically sound and affordable for TPPs and their plan members and to help manage drug spend through the appropriate selection and use of drug therapy.
22. The typical development and management of the formulary occurs with the guidance of a Pharmacy & Therapeutic (P&T) Committee or equivalent body. A P&T committee is an external advisory body of experts from across the United States usually composed of independent health care professionals with broad clinical backgrounds and/or academic expertise regarding prescription drugs.	29. The typical development and management of the formulary occurs with the guidance of a Pharmacy & Therapeutic (“P&T”) Committee or equivalent body. A P&T committee is an advisory body of experts from across the United States usually composed of health care professionals with broad clinical backgrounds and/or academic expertise regarding prescription drugs.
23. The majority of P&T members are actively practicing pharmacists and physicians. The	33. The majority of P&T members are actively practicing pharmacists and physicians. The

Centers for Medicare and Medicaid Services (CMS) also provides requirements for P&T committee composition. P&T committees are structured to provide non-biased, quality and evidence-based formulary decisions with the primary consideration being the clinical merit of the drug.	Centers for Medicare and Medicaid Services (“CMS”) also provides requirements for P&T committee composition. P&T committees are structured to provide non-biased, quality and evidence-based formulary decisions with the primary consideration being the clinical merit of the drug.
24. An example of P&T committee composition is as follows: a. 4 pharmacists (1 academic, 1 hospital, 2 geriatric); b. 18 physicians (representing broad specialties); c. Specialties represented: Allergy, Cardiology, Clinical pharmacology, Endocrinology, Family practice, Gastroenterology, Gerontology, Hematology/oncology, Internal medicine, Infectious disease, Pediatrics, Neurology, Medical ethics, Pharmacoeconomics, Pharmacology, Psychiatry, Rheumatology, Pharmacoeconomics, Pharmacology, Psychiatry, Rheumatology.	34. An example of P&T committee composition is as follows: a. 4 pharmacists (1 academic, 1 hospital, 2 geriatric); b. 18 physicians (representing broad specialties); c. Specialties represented: Allergy, Cardiology, Clinical pharmacology, Endocrinology, Family practice, Gastroenterology, Gerontology, Hematology/oncology, Internal medicine, Infectious disease, Pediatrics, Neurology, Medical ethics, Pharmacoeconomics, Pharmacology, Psychiatry, Rheumatology, Pharmacoeconomics, Pharmacology, Psychiatry, Rheumatology.
25. The P&T committee is required to base formulary decisions on scientific evidence, standards of practice, peer reviewed medical literature, accepted clinical practice guidelines and other appropriate information. All reviews are to be conducted from a purely clinical perspective involving U.S. Food and Drug Administration (FDA) approved indications.	35. The P&T committee is required to base formulary decisions on scientific evidence, standards of practice, peer reviewed medical literature, accepted clinical practice guidelines and other appropriate information. All reviews are to be conducted from a purely clinical perspective involving U.S. Food and Drug Administration (“FDA”) approved indications.
26. Typically, P&T committees meet on a quarterly basis and as needed to review issues that may arise which might impact the plan’s formulary.	36. Typically, P&T committees meet on a quarterly basis and as needed to review issues that may arise which might impact the plan’s formulary.
27. Members of a P&T committee are subject to completion of a “conflict of interest” disclosure form as well as a “non-disclosure” annual agreement.	37. Members of a P&T committee are subject to completion of a “conflict of interest” disclosure form as well as a “non-disclosure” annual agreement.
28. The below demonstrative shows how the P&T committee typically makes decisions regarding its drug formularies:  [FLOW CHART OMITTED]	38. The below demonstrative shows how the P&T committee typically makes decisions regarding its drug formularies:  [FLOW CHART OMITTED]
29. The FDA created the Approved Drug Products with Therapeutic Equivalence	47. The FDA created the Approved Drug Products with Therapeutic Equivalence

Evaluations, known as the Orange Book, as guidance in creating formularies and to regulate substitution. The first edition appeared in October 1980; a new edition is published each year and cumulative supplements are made available on a monthly basis. Named for the orange cover of the book, it is now published in electronic form and accessible on the internet (electronic format). The publication contains a list of all the drugs approved for marketing in the United States.	Evaluations, known as the Orange Book, as guidance in creating formularies and to regulate substitution. The first edition appeared in October 1980; a new edition is published each year and cumulative supplements are made available on a monthly basis. Named for the orange cover of the book, it is now published in electronic form and accessible on the internet in an electronic format. The publication contains a list of all the drugs approved on the basis of safety and effectiveness by the FDA for marketing in the United States.
30. The Orange Book lists drug products approved on the basis of safety and effectiveness by the FDA. The main criterion for inclusion of any product is that the product has a current, approved Abbreviated New Drug Application (ANDA). The Orange Book contains therapeutic equivalence evaluations for approved generic prescription drug products.	49. The Orange Book lists drug products approved on the basis of safety and effectiveness by the FDA. The main criterion for inclusion of any product is that the product has a current, approved Abbreviated New Drug Application (“ANDA”). The Orange Book contains therapeutic equivalence evaluations for approved generic prescription drug products.
31. Generic drug manufacturers are permitted to avoid the expensive and lengthy New Drug Application process (NDA) by filing an ANDA, where a generic drug must contain the same active ingredient, route of administration, bioequivalence (rate and extent of drug absorption), and other characteristics as the brand version.	50. Generic drug manufacturers are permitted to avoid the expensive and lengthy New Drug Application (“NDA”) process by filing an ANDA, when a generic drug contains the same active ingredient, route of administration, therapeutic equivalence, and other characteristics as the brand version.
32. The Orange Book consists of five main sections: an introduction, a “how to use” section, the drug product lists, appendices, and a patent and exclusivity information addendum. The drug product list consists of all approved drug products and their respective therapeutic equivalence codes.	51. The Orange Book consists of five main sections: an introduction, a “how to use” section, the drug product lists, appendices, and a patent and exclusivity information addendum. The drug product list consists of all approved drug products and their respective therapeutic equivalence codes.
33. The Orange Book has created a list of Therapeutic Equivalence (TE) Codes. These codes are as follows: <ul style="list-style-type: none"> <li>• <i>Pharmaceutical Equivalents</i>: drug products which contain the same active ingredients in the same strength and dosage form delivered by the same route of administration.</li> </ul>	54. The Orange Book has created a list of Therapeutic Equivalence (“TE”) Codes. These codes are as follows: <ul style="list-style-type: none"> <li>a. <i>Pharmaceutical Equivalents (“PE”)</i>: drug products which contain the same active ingredients in the same strength and dosage form delivered by the same route of administration.</li> </ul>

<ul style="list-style-type: none"> <li>• <i>Bioequivalent Drug Products</i>: drug products that have shown comparable bioavailability when studied under similar conditions (e.g. the rate and extent of absorption of the test drug does not significantly differ from the reference drug).</li> </ul>	<p>b. <i>Bioequivalent Drug Products (“BE”)</i>: drug products that have shown comparable bioavailability when studied under similar conditions (e.g. the rate and extent of absorption of the test drug does not significantly differ from the reference drug).</p> <p>c. <i>TE = PE + BE for same use.</i></p>
34. These TE Codes are further divided into two categories, A-rated and B-rated.	55. These TE Codes are further divided into two categories, A-rated and B-rated.
35. A-rated Drugs are those which the FDA considers to be therapeutically equivalent and, therefore substitutable where permitted by the prescriber. They are further divided as follows:	56. A-rated Drugs are those which the FDA considers to be therapeutically equivalent and, therefore substitutable where permitted by the prescriber. They are further divided as follows:
36. AA: ingredients and dosage forms presenting neither actual nor potential bioequivalence problems (e.g. oral solutions). Some dosage forms are assigned specific codes based on criteria used to demonstrate bioequivalence.	56.a. AA: ingredients and dosage forms presenting neither actual nor potential bioequivalence problems (e.g., oral solutions). Some dosage forms are assigned specific codes based on criteria used to demonstrate bioequivalence.
37. AN=aerosolized drugs, AO=injectable oil solutions, AP=injectable aqueous solutions, AT=topical products.	56.b. AN=aerosolized drugs, AO=injectable oil solutions, AP=injectable aqueous solutions, AT=topical products.
38. <b>AB rated Drugs</b> : actual or potential bioequivalence problems have been resolved through adequate in vivo and/or in vitro testing.	56.c. <b>AB rated Drugs</b> : actual or potential bioequivalence problems have been resolved through adequate in vivo and/or in vitro testing.
39. AB rated generic drugs signify that they are interchangeable with the brand drug and the manufacturers of the generic drug have adequately fulfilled the requirements as set forth by the FDA for approval.	57. AB rated generic drugs signify that they are interchangeable with the brand drug and the manufacturers of the generic drug have adequately fulfilled the requirements as set forth by the FDA for approval.
40. AB rated generic drugs are identical versions of the Reference Listed Drug (RLD) brand drugs in terms of the following: pharmacokinetic and pharmacodynamic properties, mechanism of action, efficacy, safety, dosage, strength, intended usage, and route of administration.	58. AB rated generic drugs are identical versions of the RLD brand drugs in terms of the following: pharmacokinetic and pharmacodynamic properties, mechanism of action, efficacy, safety, dosage, strength, intended usage, and route of administration.
41. TE codes followed by numbers: applied when there are two or more drug products containing the same ingredient, with the same strength and dosage form, which are not bioequivalent to each other. In such instances, there will be more than one RLD and any generic seeking approval must prove bioequivalence to one particular RLD.	60. TE codes followed by numbers: applied when there are two or more drug products containing the same ingredient, with the same strength and dosage form, which are not bioequivalent to each other. In such instances, there will be more than one RLD and any generic seeking approval must prove bioequivalence to one particular RLD.



42. In seeking approval for a brand drug through a NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book.	63. In seeking approval for a brand drug through an NDA, manufacturer applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book.
43. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA, for each patent listed in the Orange Book for the referenced drug, that: a. No patent information on the drug product that is the subject of the application has been submitted to the FDA; b. Such patent has expired; c. The date on which such patent expires or; d. Such patent is invalid or will not be infringed upon by the manufacturer, use or sale of the drug product for which the application is submitted.	65. Any generic drug manufacturer who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or 505(b)(2) NDA referencing a drug listed in the Orange Book, must certify to the FDA, for each patent listed in the Orange Book for the referenced drug, that: a. No patent information on the drug product that is the subject of the application has been submitted to the FDA; b. Such patent has expired; c. The date on which such patent expires or; d. Such patent is invalid or will not be infringed upon by the manufacturer, use or sale of the drug product for which the application is submitted.
44. A generic drug is a copy of a branded drug in terms of dosage, administration, and performance. Generic drugs must be "bioequivalent" to the branded drug, meaning the generic drug will work the same way in the body and be as safe and effective as the brand name drugs.	76. A generic drug is a copy of a branded drug in terms of dosage, administration, and performance. Generic drugs must be equivalent to the branded drug, meaning that in addition to having the same rate and extent of drug absorption, generic drugs must be the same as that of the name brand drug, be effective against the condition or illness being treated and be as safe and otherwise equivalent to the brand name drugs.
45. Substitution of generic equivalents (drugs considered bioequivalent by FDA) are encouraged by PBMs to provide the best care at an affordable cost.	77. Substitution of generic equivalents are encouraged by PBMs to provide the best care at an affordable cost. Some states require pharmacies to substitute generics unless otherwise prescribed by the physician.
46. Use of generic drugs that have been deemed bioequivalent by the FDA does not require a new round of review or approval by a P&T committee, because the TPPs and P&T Committees expressly rely upon the manufacturers' compliance with all applicable standards, obligations, and regulations.	78. Use of generic drugs that have been deemed bioequivalent by the FDA does not require a full new round of review or approval by a P&T committee, because the TPPs and P&T Committees expressly rely upon the manufacturers' compliance with all applicable standards, obligations, and regulations.

49. When the FDA approves a drug, it is deemed to be safe and effective to use.	89. When the FDA approves a drug, it is deemed to be safe and effective to use.
50. For generics, FDA approval means that a drug is not only deemed to be safe and effective but also bio-equivalent.	90. For generics, FDA approval means that a drug is not only deemed to be safe and effective but also bioequivalent.
51. In order to obtain FDA approval of a generic drug as an Orange Book listed drug, a manufacturer is required to demonstrate that its generic drug is bioequivalent to the RLD.	91. In order to obtain FDA approval of a generic drug as an Orange Book listed drug, a manufacturer is required to demonstrate that its generic drug is bioequivalent to the RLD.
54. Maintaining equivalence to the RLD is an ongoing requirement.	98. Maintaining equivalence to the RLD is an ongoing requirement.
Summary Op. A. The safety of a medication must be proven by the manufacturer to the FDA so that the medication may receive approval.	Summary Op. I. I. The safety of a medication must be proven by the manufacturer to the FDA so that the medication may receive approval. This information serves as an assurance that the medication meets the quality standards outlined by FDA.
Summary Op. C. Manufacturers have ultimate responsibility for their quality process and the information presented in the ANDA which is reported to the FDA to obtain approval.	Summary Op. III. Manufacturers have ultimate responsibility for their quality process, manufacturing practices, safety obligations and all of the information presented in the ANDA which is reported to the FDA to obtain approval.
Summary Op. E. TPPs, PBMs and P&T committees rely on the FDA approval as the indicator that the medication may be considered for formulary placement and plan coverage/reimbursement.	Summary Op. VI. TPPs, PBMs and P&T committees rely on the FDA approval as the indicator that the medication may be considered for formulary placement and plan coverage/reimbursement.
Summary Op. F. The Orange Book lists the FDA approved generics of the original brands. These FDA approved generics can be put on a prescription drug formulary and/or plan coverage for reimbursement.	Summary Op. VII. The Orange Book lists the FDA approved generics of the original brands. The pharmaceutical industry, including TPPs, are meant to be able, by design, to rely on the information in the Orange Book such that these FDA approved generics can be put on a prescription drug formulary and/or plan coverage for reimbursement.